IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF VIRGINIA

MARY SHARON WALKER,

Plaintiff,

VS.

NEW ENGLAND COMPOUNDING PHARMACY, INC., D/B/A/ NEW ENGLAND COMPOUNDING CENTER,

and

IMAGE GUIDED PAIN MANAGEMENT, P.C., D/B/A INSIGHT IMAGING ROANOKE,

Defendants.

Civil Action No: 7:12CV00564

MOTION TO REMAND TO ROANOKE CITY CIRCUIT COURT

PLAINTIFF'S MOTION TO REMAND AND SUPPORTING BRIEF

Plaintiff, by her attorneys, THE MILLER FIRM, LLC, files this Motion for Remand against Defendants, and states as follows:

I. BACKGROUND

Plaintiff filed a complaint in the Roanoke City Circuit Court in the Commonwealth of Virginia on October 23, 2012, against Defendants for injuries and damages suffered after Plaintiff was injected with methylprednisolone acetate, a steroid pain reliever manufactured, distributed and sold by the Defendants. Specifically, the Plaintiff alleges that the defective methylprednisolone acetate was contaminated with a fungus, causing Plaintiff to suffer from fungal meningitis. Defendant Image Guided Pain Management, P.C., D/B/A Insight Imaging Roanoke (hereinafter "Insight"), is a Virginia corporation with its principle place of business in

Roanoke, Virginia and is, therefore, a citizen of Virginia. *See*, Compl. at ¶ 4, attached hereto as "Exhibit A".

On November 15, 2012, Defendant New England Compounding Pharmacy, Inc., D/B/A New England Compounding Center (hereinafter "NECC") removed this action to Federal Court claiming that: (1) Ms. Walker's complaint asserts claims arising under the laws of the United States pursuant to 28 U.S.C. 1331; and (2) that Plaintiff fraudulently joined the Virginia Defendant, Insight, and as a result this Court has subject matter jurisdiction over this action on the basis of diversity jurisdiction pursuant to 28 U.S.C. § 1332.

Plaintiff now respectfully requests this Court remand this case back to the Roanoke City Circuit Court pursuant to 28 USCS § 1447, because the Court does not have jurisdiction over this case. The Complaint filed in Roanoke City Circuit Court raises absolutely no claims against NECC for violating federal law. Moreover, NECC's arguments and authorities relating to the alleged fraudulent joinder of Insight Imaging were previously considered and rejected by the U.S. District Court for the Eastern District of Virginia in *Sanders v. Medtronic, Inc.*, 2006 U.S. Dist. LEXIS 45516 (E.D. Va. 2006), which held that it is reasonably possible that a hospital may be liable as a seller in a product liability claim under Virginia law. Because Plaintiff has viable claims against Insight Imaging, which is a Virginia citizen, the Court lacks diversity jurisdiction and should remand this case to the Roanoke City Circuit Court.

II. STANDARD FOR REMOVAL

In applying 28 USCS § 1447(c), the Fourth Circuit has held that "We are obligated to construe removal jurisdiction *strictly* because of the significant federalism concerns implicated. Therefore, if federal jurisdiction is doubtful, a remand [to state court] is necessary." *Gen. Tech. Applications v. Exro Ltda.*, 388 F.3d 114, 118 (4th Cir. 2004) [(quoting *Dixon v. Coburg Dairy*,

Inc., 369 F.3d 811, 816 (4th Cir. 2004) (en banc) (emphasis added)]. "Likewise, it is equally well-settled that the parties' characterization of themselves or their claims is not determinative for federal jurisdiction purposes." *Id.* (quoting *Roche v. Lincoln Prop. Co.*, 373 F.3d 610, 615-16 (4th Cir. 2004)).

"The burden on the defendant claiming fraudulent joinder is heavy: the defendant must show that the plaintiff cannot establish a claim against the nondiverse defendant even after resolving all issues of fact and law in the plaintiff's favor. A claim need not ultimately succeed to defeat removal; only a possibility of a right to relief need be asserted."

Marshall v. Manville Sales Corp., 6 F.3d 229, 232-233 (4th Cir. 1993).

ARGUMENT

A. Plaintiff's complaint raises no issues of federal law that could confer jurisdiction to this court under 28 U.S.C. 1331. Therefore, this case should be remanded.

Whether a claim "arises under" federal law must be determined by reference to the "well-pleaded complaint." *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 808 (U.S. 1986) (citing *Franchise Tax Board*, 463 U.S., at 9-10). It is well-established that a defense that raises a federal question is inadequate to confer federal jurisdiction. *Id.* (citing *Louisville & Nashville R. Co. v. Mottley*, 211 U.S. 149 (1908)).

The Plaintiff's "well pleaded complaint" in this case unequivocally shows there are no claims against NECC that would require the application of a federal statute, or even so much as a federally imposed standard of care. First and foremost, the Complaint specifically identifies NECC as a "compounding pharmacy", which is not subject to FDA regulation, and whose products "are not subject to approval by the Food and Drug Administration." Compl. at ¶12-13. The Complaint further sets forth claims under Virginia law for negligence, product liability, and breach of express and implied warranties. The factual basis for NECC's liability under these

various causes of action is NECC's negligent compounding process, which produced contaminated batches of prednisolone acetate, which it then sold to Defendant Insight. These claims are not based on NECC's potential violation of federal law or federal regulations.

What is remarkable about NECC's Notice of Remand in this case is that it <u>agrees with</u> the Plaintiff's allegation that it is a compounding pharmacy not subject to FDA regulation. Not. of Removal at ¶11 ("NECC maintains that its compounding practices conformed to all applicable standards for compounding pharmacies..."). NECC then argues that because it *might* be determined at some future date to be subject to increased federal regulation, that possibility raises an "important federal interest" this case. Not. of Removal at ¶5. However, NECC fails to explain why this "important federal interest" should have any impact on the outcome of this case.

The only allegation regarding NECC's potential violation of FDA regulations relates strictly to the Plaintiff's claim of negligence against <u>Insight</u> for carelessly purchasing its medications from NECC: "Despite NECC's history of improper practices, Insight Imaging negligently purchased steroids from NECC when it knew or should have known that its products were not reasonably safe to administer to its patients." Compl. at ¶41. These allegations raise no issues of federal law that would subject this case to federal question jurisdiction pursuant to 28 U.S.C. 1331.

NECC further argues that FDA regulation could possibly lead to federal pre-emption of the Plaintiff's state law claims under the holding in *PLIVA*, *Inc. v. Mensing*, 131 S. Ct. 2567, 2572, 180 L. Ed. 2d 580 (2011). *Mensing* involved state common law claims that generic drug manufacturers failed to provide adequate warning labels for generic metoclopramide. *Id.*, 131 S. Ct. 2567, 2572, 180 L. Ed. 2d 580 (2011). The state common law at issue in *Mensing* required a drug manufacturer that was or should be aware of its drug's danger to label the drug in a way that

renders it reasonably safe. *Id.* at 2573. At issue was whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state law claims. *Id.* at 2572. The Supreme Court held that they do because it was impossible to comply with both federal law and state warning label requirements. *Id.* at 2577.

Again, NECC fails to identify which FDA regulation in particular might serve to preempt the Plaintiff's state law claims under *Mensing*. Rather, NECC cites to a warning letter the FDA wrote in 2008 to a <u>different</u> compounding pharmacy as in indication of possible future enforcement action by the FDA against NECC. Not. of Removal at ¶ 8.

Recently, in *In Re: New England Compounding Pharmacy Cases*, Docket No. 12-12052-FDS, the U.S. District Court for the District of Massachusetts issued an order remanding the lawsuit brought by Michigan residents against NECC for exactly the same causes of action as the Plaintiff asserts in the present case; negligence, product liability, and breach of warranty related to NECC's manufacture and distribution of prednisolone acetate contaminated by fungus. *See*, Order on Plaintiff's Motion to Remand (Saylor, J.), attached hereto as "Exhibit B". In his order, Judge Saylor noted that the Plaintiffs' complaint "asserts claims under Massachusetts law for negligence and breach of implied warranty. It does not refer to federal law, or any potentially applicable federal regulation or standard".

The Plaintiff respectfully suggests this Court reach the same conclusion as Judge Saylor in Massachusetts, and remand this case back to the Roanoke City Circuit Court. This case, like the cases in front of Judge Saylor, does not refer to federal law, or any potentially applicable federal regulation or standard as a basis for liability.

B. Because Plaintiff Has Asserted Viable State Law Claims Against A Virginia Defendant, This Court Lacks Diversity Jurisdiction Under 28 U.S.C. § 1332.

Defendants misleadingly argue that "Plaintiffs reliance on breach of implied warranty to establish Insight's alleged liability has been rejected by Virginia courts." Not. of Removal at ¶19. To support its argument that "Virginia courts" have rejected such a claim, NECC then cites to exactly one unreported Virginia circuit court opinion, *Gressman v. Peoples Serv. Drug Stores*, Inc., No. LL-692-4, 1998 WL 619115. This precise argument was rejected by the U.S. District Court for the Eastern District of Virginia in *Sanders v. Medtronic, Inc.*, 2006 U.S. Dist. LEXIS 45516 (E.D. Va. 2006).

In Sanders, the Court decided that there is a possibility that a defendant health care provider can be liable as a seller of a defective product in Virginia. *Id.* at *30. The Court considered, and rejected, the same authority that NECC now relies upon to support its arguments in favor of removal. For example, the Court in Sanders extensively considered Gressman v. Peoples Service Drug Stores, Inc., 10 Vir. Cir. 397 (Va. Cir. Ct. 1988). In Gressman, the circuit court held that a pharmacist could not be held liable for breach of warranty for dispensing the wrong drug to the plaintiff because as a "health care provider", the pharmacist was engaged primarily in the business of providing a service, rather than the sale of goods. *Id.* at 409.

The Court in *Sanders* held that *Gressman* provided an insufficient legal basis to conclude that Sanders' claim for breach of warranty had "no possibility" of succeeding in Virginia:

As to *Gressman*, the court recognizes that the circuit court found that a pharmacist, as a health care provider, is primarily a provider of services, rather than a seller of goods. However, the court does not feel that a circuit court case from 1988 involving the liability of a pharmacist for breach of warranty is compelling enough for this court to say with certainty that a Virginia court could not reasonably find that Sentara, a hospital, is a "seller" of goods in the instant

case. ... Gressman does not convince this court that a hospital cannot be a "seller" under Virginia law. Accordingly, with respect to Medtronic's argument that Sentara is not a "seller", the court finds that the Virginia case law set forth by Medtronic is insufficient to convince this court that there is no reasonable possibility that a Virginia court could find that Sentara is a "seller" of Medtronic IPG devices in this case."

Id. at *20-21.

Defendant cites only one other case to support its fraudulent joinder argument, Commonwealth Dep't of Taxation v. Bluefield Sanitarium, Inc., 222 S.E.2d 526 (1976). Blue Field Sanitarium was a tax case, in which the court considered whether the sales tax exemption for purchase of medical supplies applied to private hospitals. Id. at 687. The Court held that the provision of the tax code on which the hospital was attempting to avoid paying sales tax was intended to benefit patients, not hospitals engaging in the provision of health care services. Id. at 690.

The court in *Sanders* carefully analyzed *Bluefield Sanitarium* and concluded it does not answer the relevant question of whether a health care provider is a seller of goods under the U.C.C.:

As to Bluefield Sanitarium, this court,.... is concerned by the fact that Bluefield Sanitarium is a tax case which was decided under completely different policy considerations and had nothing to do with a hospital's potential liability for breach of warranty or an individual's right to recover for her injuries. Although the Supreme Court of Virginia might be compelled to consider its analysis in Bluefield Sanitarium in deciding the instant case, *Bluefield Sanitarium* is significantly distinguishable from the instant case for this court to conclude that there is no reasonable possibility that the Supreme Court of Virginia would find that Sentara is not a seller under the U.C.C.

Sanders, at *20.

The burden is on the non-moving party to negate the possibility of recovery, and as long as there is a "glimmer of hope for the plaintiff, the jurisdictional inquiry ends." *Hartley v. CSX*

Transportation, Inc., 187 F.3d 422, 426 (4th Cir. 1999). Applying the foregoing criteria, the Court in *Sanders* concluded that the defendant Medtronic failed to meet its burden of showing there was no possibility of recovery against a Virginia hospital for breach of warranty as a seller of goods.

Sanders is directly on point to the present case, yet NECC fails to even acknowledge its existence in its Notice of Removal. No pertinent changes to Virginia law have been made since Sanders was decided. Moreover, subsequent analogous Federal Court decisions in other districts have since supported the reasoning in Sanders. See, e.g., Phillips v. Medtronic, Inc., 2010 U.S. Dist. LEXIS 127961 *12 (D. Mass. Dec. 1, 2010) (remanding case because there was no definitive state case law as to whether a hospital can be liable on breach of warranty claim); Snyder v. Davol, Inc., 2008 U.S. Dist. LEXIS 1675 (D. Or. Jan. 7, 2008) (remanding case because there was no definitive state case law as to whether a healthcare provider can be liable on a products liability claim). Plaintiff asks this Court to follow Sanders and remand this case to the Circuit Court for the City of Roanoke.

CONCLUSION

Defendant has failed to meet its heavy burden of demonstrating that this Court should exercise jurisdiction over this matter. The Plaintiff's Complaint raises no issues of federal law justifying the exercise of federal question jurisdiction under 28 U.S.C. § 1331. Defendant has also failed to meet its heavy burden of showing that the Plaintiff has no possibility of recovery against Insight Imaging under Virginia law. It is reasonably possible that Insight Imaging can be held liable as a seller on breach of warranty claims. For the aforementioned reasons, the Court

should remand this case back to the Roanoke City Circuit Court of the Commonwealth of Virginia.

Respectfully Submitted by:

/s/ Jeffrey Travers

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CERTIFICATE OF SERVICE

I hereby certify that on December 17, 2012, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system and that electronic notice and service will be completed through the ECF system to all counsel of record.

/s/ Jeffrey Travers, Esq.

Jeffrey Travers, Esq. VSB # 77409